IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application

Inventors: David Feygin et al.

Serial No.: 10/807016

Conf. No.: 4798

Filing Date: 3/23/2004

Art Unit: 3714

Examiner: Kesha Frisby

Docket No.: 115-004US

Title: Vascular-Access Simulation System with Ergonomic Features

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Enclosed are papers related to the above-identified patent application:

Pursuant to 37 CFR 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time.

Respectfully,

David Feygin et al.

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Dear Sir:

REPLY BRIEF UNDER 37 CFR 41.41

Pursuant to 37 CFR 41.41, this brief is filed in response to a new ground of rejection issued by the Examiner.

The Examiner's *Answer Brief* raises several new grounds of rejection. Appellant's response to these new grounds of rejection is contained in this *Reply Brief*.

Furthermore, the Examiner's *Answer Brief* contains a section, beginning at page 16, entitled "Response to Argument" in which the Examiner attempts to rebut arguments presented by appellant. These "rebuttals" are based on a misreading of the references and/or the misapplication of the patent laws. This *Reply Brief* addresses some of these rebuttals. Silence on the part of appellant as to any of the Examiner's allegations should not be interpreted as acquiescence or agreement therewith. To the extent that appellant does not address a rebuttal argument, appellant is content to rely on its remarks in the *Appeal Brief.*

New Grounds of Rejection

The Examiner issued the following new grounds of rejection in the case on appeal:

1. Claim 25 is rejected under 35 USC §103 as being obvious over U.S. Pat. No. 6,470,302 to Cunningham *et al*. in view of U.S. Pat. No. 6,654,000 to Rosenberg.
2. Claims 28, 33, and 34 are rejected under 35 USC §103 as being obvious over Cunningham *et al*. in view of Rosenberg and further in view of U.S. Publ. Pat. App. No. 2003/0031993 to Pugh.

Appellant's Response to the New Grounds of Rejection

Ground 1. Claim 25 recites an apparatus comprising:

> a housing, wherein said housing has an opening in an uppermost surface thereof;
>
> pseudo skin, wherein said pseudo skin covers said opening;
>
> an end effector, wherein said end effector is inserted into said housing through said pseudo skin during the performance of a simulated vascular-access procedure; and
>
> a plurality of mechanisms, wherein said plurality of mechanisms are contained completely within said housing and are covered by said pseudo skin, and wherein said plurality of mechanisms include:
>
> (a) a first mechanism is for simulating a skin-stretch technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin; and
>
> (b) a second mechanism for receiving said end effector.

The Examiner reaches at least four erroneous conclusions (identified as items "**A**," "**B**," "**C**," and "**D**" below) with respect to what the prior art discloses/suggests. These erroneous conclusions form the basis for her finding that claim 25 is obvious over the cited art.

The Examiner alleges that Cunningham *et al*. discloses:

(i) a housing (case 32);
(ii) an opening in an uppermost surface of the housing;
(iii) pseudo skin (belt 108);
(iv) a plurality of mechanisms, including:
    (a) a first mechanism for simulating a skin stretch technique that is used in conjunction with a vascular access procedure and is performed on the pseudo skin; and
    (b) a second mechanism for receiving the end effector.

The Examiner admits that Cunningham *et al*. does NOT disclose that:

1. the pseudo skin covers the opening (item ii above);
2. the end effector is inserted into the housing through the pseudo skin;
3. the plurality of mechanisms are contained completely within the housing; and
4. the plurality of mechanisms are covered by the pseudo skin.

The Examiner, however, asserts that Rosenberg teaches:

(vii) pseudo skin covers the opening (col. 5, lines 38-47); and
(viii) the end effector is inserted into the housing (the "body" of the patient) through the pseudo skin.

The Examiner concludes, based on allegations (vii) and (viii), that it would have been obvious to incorporate in Cunningham *et al.* that:

A. the pseudo skin covers the opening; and
B. the end effector is inserted into the housing through the pseudo skin (during the performance of a vascular access procedure.

Appellant disagrees with conclusions **A** and **B** because, among any other reasons, allegations (vii) and (viii) are incorrect:

- Allegation (vii). Pseudo skin does not cover "an opening in the uppermost surface of the housing" because, among any other reasons, Rosenberg does not disclose a housing. But the Examiner alleges otherwise, asserting that Rosenberg discloses a housing that contains a plurality of mechanisms. At page 22 of her Answer Brief, the Examiner states: "*column 5 lines 41-47 & lines 54-57 of Rosenberg specifically state that these components are within the body of the patient. The Examiner does agree that a barrier is not a housing however, the above cited lines indicate the mechanisms are within the body of the patient which is the housing*."

  The above-cited lines indicate no such thing. There are no "mechanisms" in the body of a patient—whether for performing a skin stretch or anything else—a patient's body contains organs, blood, bone, and tissue.

  The disclosure states, at lines 41-42 that the "*barrier 22 is used to represent [a] portion of the skin covering the body of the patient*." That doesn't say there is a body present or a housing present. It simply explains the significance of the barrier.

  At lines 42-47, the disclosure explains what a trocar is used for: "*Trocar 24 is inserted into the body of the patient to provide an entry and removal point from the body of the patient for the laparoscopic tool 18, and to allow manipulation of the laparoscopic tool 18 within the body of the patient while minimizing tissue damage*." (emphasis added.)

  "Housings" don't suffer tissue damage; live patients do. This passage is not suggesting that there is an actual body present nor does the passage suggest or state that a housing is present. It simply explains the use of a trocar, which is difficult to explain without reference to a body.

  Lines 54-57 state that a "gimbal apparatus 25 is shown within the "body" of the patient in phantom lines. If Rosenberg's system included a housing, the disclosure would refer to it. There is, however, no housing present. As a consequence, the disclosure references an imaginary body. The disclosure places the word "body" in quotes to indicate that it is not actually present.

- Allegation (viii). Claim 1 recites, in pertinent part, "an end effector, wherein said end effector is inserted into said housing through said pseudo skin during the performance of a simulated vascular-access procedure." The highlighted language is important. The Examiner chose to ignore this important limitation.

  The fact is, neither Rosenberg nor Cunningham disclose or suggest inserting the end effector into a housing through pseudo skin during a simulated vascular-access procedure.

  As to Rosenberg, (1) there is no housing; and (2) the end effector is not inserted through pseudo skin during any simulated vascular access procedure. As noted at col. 5, line 60 – col. 6, line 3:

  > The present invention is concerned with tracking the movement of the shaft portion (28) in three-dimensional space, where the movement has been constrained such that the shaft portion (28) has only three or four free degrees of freedom. This is a good simulation of the use of a laparoscopic tool (18) in that **once** it is inserted into a trocar (24) **and through the gimbal apparatus (25)**, it is limited to about four degrees of freedom. More particularly, the shaft (28) is constrained at some point of along its length such that it can move with four degrees of freedom within the patient's body. (Emphasis added.)

  This passage indicates that the laparoscopic (18) is inserted through the trocar (24) and into the gimbal apparatus (25) to limit motion before the simulated vascular access procedure begins. This is typical for this type of system due to the difficulty in decoupling an end effector from its force feedback system.

  Also, at col. 3, lines 36+ (and col. 12, lines 3+), Rosenberg discloses a method for providing a human/computer interface for use as a simulatioin tool. This is not a method of use; rather, it is measure for making the simulator. The first step in the method is:

  > defining an origin in 3-dimensional space.

  This corresponds to origin (O) at the intersections of axes A_1 and A_2 in FIG. 2 of Rosenberg.

The second step of the method pertains to constraining the object in 3-dimensional space:

> physically constraining a shaft that can be grasped by an operator such that a portion of the object always intersects the origin ….
>
> (Emphasis added.)

These initial steps are not steps that are performed each time a simulation is performed. Rather, these steps pertain to the set-up of the simulator itself. They are consistent with the passage cited previously at col. 5, lines 60+, and demonstrate that the end effector (*e.g.*, laparoscopic tool, *etc*.) is NOT inserted into the (non-existent) housing through pseudo skin DURING the performance of a simulated vascular-access procedure.

It is further noted that the laparoscopic tool does to engage any of Rosenberg's sensors that monitor the movement thereof until after the tool has passed through aperture (46). (*See*, *e.g.*, FIG. 2.) The system cannot simulate anything until the tool engages the sensing system, which is well after the tool "penetrates" the barrier.

It is notable that the Cunningham simulator suffers from the same drawback, as noted at para. [0009] of U.S. Pat. Application S.N. 10/807,047, which is incorporated by reference into the case on appeal:

> A second shortcoming of the '302 is that the end effector (i.e., the catheter unit assembly) is permanently coupled to the force-feedback system. Although not atypical for this type of system (i.e., haptics devices) due to the difficulty of de-coupling an end effector from its force-feedback system, this is very undesirable because to truly mimic most "actual" systems, de-coupling is necessary.
>
> Indeed, in an actual vascular access procedure, the end effector—the needle/catheter—is not inserted into the arm until the procedure actually begins. In applicant's claimed invention, such decoupling is achieved, which is described in detail in related U.S. patent applications that are incorporated by reference into the case on appeal.

Since there is no pseudo skin covering the opening of the housing in Cunningham and since Rosenberg doesn't disclose a housing, the combination of these references cannot be said to disclose or suggest the limitation of claim 25 that pseudo skin covers an opening in an uppermost surface of the housing.

Cunningham doesn't insert an end effector through pseudo skin. Rosenberg doesn't disclose a housing or a vascular access procedure. Neither Cunningham nor Rosenberg inserts an end effector into anything during the performance of a vascular access procedure; any "insertion" occurs before the procedure starts. As a consequence, the combination of Cunningham and Rosenberg does not discloses or suggest that an end effector is inserted into a housing through a pseudo skin during the performance of a simulated vascular-access procedure.

Furthermore, the Examiner admits that Cunningham *et al.*/Rosenberg do not disclose that:

5. the plurality of mechanisms are contained completely within the housing;
6. the plurality of mechanisms are covered by the skin.

Yet, the Examiner concludes that it would have been obvious to incorporate in Cunningham *et al.* that:

C. the plurality of mechanisms are contained completely within the housing; and
D. the plurality of mechanisms are covered by the pseudo skin.

The Examiner's support for conclusions C and D is that the appellant allegedly:

> *has not disclosed that having … said plurality of mechanism [are] contained completely within said housing and are covered by said pseudo skin provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Cunningham's system, and applicant's invention, to perform equally well with either wherein said plurality of mechanisms are contained partially within said housing and are covered by said pseudo skin taught by Cunningham et al. or the claimed [invention] wherein said plurality of mechanisms are contained completely within said housing and are covered by said pseudo skin because both said plurality of mechanisms contained within said housing and are covered by said pseudo skin would perform the same function of performing a vascular access procedure.* (emphasis added.)

The Examiner's and the Board's attention is directed to the following sections of appellant's specification, beginning with the "Background" section at paragraphs [0006]-[0009], which provides a "stated problem:"

> [0006] The simulation system that is disclosed in the '302 [Cunningham] patent has many shortcomings that substantially limit its utility as a training or accreditation tool. One shortcoming of that simulation system relates to ergonomics.
>
> [0007] In particular…. This is due, among other reasons, to the height of the interface device, which is a consequence of the layout and design of the mechanisms that compose the interface device.
>
> [0008] Furthermore, the relative positioning and arrangement of mechanisms with which a user of that system interacts to practice a vascular access procedure is not ergonomic. Specifically, the simulation system enables a user to perform needle "insertion" as well as a "skin-stretch" technique….
>
> [0009] In the system that is disclosed in the '302 patent, the skin-stretch mechanism, which includes a belt —a mock skin—, resides within a casing that is attached to and separate from the housing in which the needle-insertion procedure is practiced. To simulate the skin-stretch technique, a user "stretches" the mock skin. In comparison with an actual procedure, the location at which a user stretches the mock skin is rather remote from the needle "insertion point." Furthermore, the surface of the mock skin is not co-planar with or at the same height as the needle insertion point. In an actual procedure, of course, they are (*i.e.*, the skin surface is the insertion point). This structural arrangement does nothing to promote a user's "suspension of disbelief" and does not provide a particularly realistic simulation.
>
> (Emphasis Added.)

Thus, the specification discloses a problem; that is, prior art vascular-access simulators are inconsistent with human anatomy. This makes it more difficult for a user to suspend disbelief (that the simulation is not really an actual procedure) and results in ergonomically-incorrect hand positions during the simulation.

The specification provides a solution, disclosed in the Summary section, at paragraphs [0012]-[0015]:

> [0012] The illustrative embodiment of the present invention is a simulation system that provides realistic training and practice for performing vascular-access procedures without using human subjects. Unlike some other prior-art

simulation systems, the system is designed to provide ergonomically-correct hand position….

[0014] In accordance with the illustrative embodiment, the various mechanisms within the haptics device are configured so that one or more of the following conditions are met:

- The ….
- The shape of the haptics device is not overtly inconsistent with human anatomy (*e.g.*, an arm, *etc.*)…
- The various mechanisms of the haptics device are beneath the "skin" of the haptics device.

[0015] Simulators described herein therefore more closely simulate a real vascular-access procedure than simulators in the prior art. This more realistic simulation is expected to result in a more useful training experience.

(Emphasis added.)

Thus, the specification discloses a solution to the problem: provide a device that is designed to ensure proper hand position and that is not overtly inconsistent with human anatomy. Specifics of this solution include ensuring that:

(1) the housing is an appropriate shape/size; and

(2) to make sure that all mechanisms are within the housing and beneath the skin.

The advantage of doing this is, as stated: "[to] more closely simulate a real vascular-access procedure than simulators in the prior art. This more realistic simulation is expected to result in a more useful training experience."

See, *also*:

Para. [0035]: To the extent that some embodiments of simulator **100** are intended for use as a practice and training tool, it is advantageous for haptics device **102** to simulate vascular-access procedures as realistically as possible and provide a quantitative measure of the user's performance of the simulated procedure. To this end, haptics device **102** possesses one or more of the following attributes, in addition to any others:

- It … is at least subtly suggestive of human anatomy and does not present any substantial departures therefrom so as to support a user's ability to suspend disbelief during a simulated vascular-access procedure.

Para. [0039]: The functional elements of haptics device **102** listed above that relate to human anatomical features or are otherwise intended to generate resistive forces that would be sensed when penetrating such anatomical features (elements **222** – **228**) are advantageously contained within housing **216** ....

Para. [0043]: Pseudo skin **220** is disposed adjacent to the inside surface of housing **216** so that it appears to be nearly co-extensive (*i.e.*, co-planar) with housing **216** at openings **330** and **332**. This is intended to create a subtle suggestion that the surface of housing **216** is "skin" at regions other than where pseudo-skin **220** is accessed for skin-interaction techniques. Consistent with human anatomy, the remaining functional elements of haptics device **102** (elements **222** – **228**), with the exception of needle/catheter module **218**, are "hidden" beneath pseudo skin **220**.

Para. [0054]: It is the inventors' belief that, to the extent a user's interaction with haptics device **102** more closely tracks a practitioner's experience of performing the actual procedure (that the device is designed to simulate), the training experience is more useful. In this regard, the utility of a device such as haptics device **102** is enhanced by a design that is heavily influenced by form-function considerations and ergonomics. And, to that end, the illustrative embodiment of haptics device **102** has been strongly influenced by such considerations. In particular, and as described more fully below, considerations such as the positions of the functional modules (*e.g.*, modules **222**, **224**, **226**, *etc.*) relative to one another and relative to pseudo skin **220**, as well as the shape and dimensions of housing **216** have been taken into account in the design of haptics device **102**.

Para. [0056]: …Consistent with human anatomy, the remaining functional elements of haptics device **102** (elements **222** – **228**), with the exception of needle/catheter module **218**, are "hidden" beneath pseudo skin **220**.

The Examiner's allegation that appellant "has not disclosed that having … said plurality of mechanism [are] contained completely within said housing and are covered by said pseudo skin provides an advantage, is used for a particular purpose, or solves a stated problem" is, quite frankly, rather stunning. The specification provides, as a solution to "a stated problem," explicit statements related to the "advantages" and "particular purpose" for positioning the subject mechanisms in the claimed location. Furthermore, And it even begins with the title: "Vascular-Access Simulation System with Ergonomic Features."

Since the Examiner's conclusions at **C** and **D** are based, in part, on her erroneous statement that appellant "*has not disclosed that having … said plurality of mechanism [are] contained completely within said housing and are covered by said pseudo skin provides an advantage, is used for a particular purpose, or solves a stated problem,*" those conclusions are in error.

If only one of the Examiner's conclusions at **A-D** is incorrect, it provides a sufficient basis for the Board to reverse the rejection of claim 25. Appellant has, in fact, demonstrated that all of the Examiner's conclusions **A-D** are unsupported and incorrect. The Board is therefore requested to reverse the Examiner's rejection of claim 25 under 35 USC §103.

Ground 2. Claim 28 recites:

> The apparatus of claim 25 wherein said mechanism includes a third mechanism for simulation at least one of a palpation or an occlusion technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin, and wherein said end effectors is at least one of either a needle or a catheter.

Claim 28 recites three mechanisms:

1) a first mechanism for performing skin stretch (via claim 25);
2) a second mechanism for receiving the end effector (via claim 25); and
3) a third mechanism for simulating a palpation or occlusion technique that is used in conjunction with a simulated vascular-access procedure, performed on the pseudo skin, and the end effector is at least a needle or a catheter.

As previously discussed, neither Cunningham, Rosenberg nor the combination thereof discloses a variety of limitations recited in claim 25. A third patent by Pugh, which is combined with Cunningham and Rosenberg by the Examiner to reject claim 28, fails to cure the deficiencies of Cunningham and Rosenberg with respect to claim 25. As a consequence, claim 25, and therefore claim 28, are allowable over the combination of these three references.

As to the specifics of claim 28 and Pugh, the Examiner alleges that Pugh teaches:

(i) a third mechanism (a sensor) for simulating palpation or occlusion techniques;
(ii) as used in conjunction with a simulated vascular access procedure; and
(iii) performed on pseudo skin.

The palpation techniques disclosed by Pugh are not for use in conjunction with a vascular access procedure. Appellant has discussed this issue extensively in its

Appeal Brief. Pugh discusses "palpation" in the context of "surface abdominal, intra-abdominal and soft tissue exams." (Para. [0061].)

More particularly, Pugh discloses palpation as practiced during surgery to discriminate between a tumor and blood vessel. The "palpation" being referenced here occurs *within* the body; that is, directly on the tumor and blood vessel. As such, it is not properly termed a *skin* interaction technique (since there is no interaction with "skin") nor is performed in the context of a vascular access procedure. As discussed in the *Appeal Brief*, a vascular access procedure involves the insertion of a flexible thin plastic tube, or catheter, into a blood vessel to provide a painless way of drawing blood or delivering drugs and into a patient's bloodstream over a period of weeks, months or even years.

Pugh also discusses "surface abdominal" and "soft tissue" (*i.e.*, breast) palpation. Yet such techniques are not "in conjunction with a vascular access procedure." And that is important because neither of the "surface" palpation techniques disclose by Pugh is performed in the manner of a palpation technique when used in conjunction with a vascular access procedure. (*See*, *e.g.*, [0061].)

Simply put, Pugh does not disclose a device that is capable of providing the functionality recited in claim 28. That is, Pugh does not disclose a mechanism that is suitable for performing a palpation or occlusion technique that is performed in conjunction with a vascular access technique on pseudo skin.

Combining the teachings of Pugh with Cunningham and Rosenberg does not yield what is recited in claim 28. As a consequence, the Board is requested to reverse the rejection of claim 28.

Claim 33 recites:

> The apparatus of claim 28 wherein said housing has an anterior end and a posterior end, wherein in use, said anterior end is proximal to a user, and wherein a portion of said second mechanism is flanked by said first mechanism proximal to said anterior end and said third mechanism proximal to said posterior end.

Claim 33 is allowable based on its dependence on claims 25 and 28, which have both been shown to be allowable over the references relied upon to reject claim 33.

Regarding the specific limitations of claim 33, recall that the first mechanism is the skin-stretch mechanism, the second mechanism is the receiver for receiving the end effector, and the third mechanism is palpation/occlusion.

Cunningham discloses a housing, a receiver and a skin stretch mechanism. Rosenberg discloses a receiver and no housing. Pugh discloses unrelated palpation techniques and in that regard, does not disclose a mechanism that can perform the recited functionality.

It is not understood how the combination of these three references could possibly teach the specific placement of the three mechanisms in appellant's claimed housing, as recited in claim 33. Appellant's layout is based on technical and ergonomic considerations that are not mentioned in any of the references that the Examiner relies upon.

In view of the foregoing, the Board is requested to reverse the rejection of claim 33.

Claim 34 recites:

> The apparatus of claim 28 wherein:
>
> a user interacts with said first mechanism at a first site on said pseudo skin;
>
> said user interacts with said second mechanism at a second site on said pseudo skin;
>
> said user interacts with said third mechanism at a third site on said pseudo skin; and
>
> locations of each of said first site, second site, and third site on said pseudo skin correspond to locations of said first mechanism, second mechanism, and third mechanism, respectively, within said housing.

Claim 34 recites that the sites on the pseudo skin at which a user interacts with the various mechanisms corresponds to the locations of the mechanisms within the housing.

Claim 34 is allowable based on its dependence on claims 25 and 28, which have both been shown to be allowable over the references relied upon to reject claim 34.

Regarding the specific limitations of claim 34, consider that Cunningham discloses two of the recited mechanisms, but the user only interacts with one of them at a site on the pseudo skin. Rosenberg discloses only one of the recited mechanisms and Pugh, although disclosing unrelated palpation techniques, does not disclose any mechanism that can perform the recited function.

As a consequence, the combination of these references cannot be found to disclose or suggest what is recited in claim 34. The Board is therefore requested to reverse the rejection of claim 33.

Appellant's Response to Examiner's Rebuttals

Ground 1. The Examiner states that "the claims currently presented [are] unclear as to how the first device/first mechanism/plurality of mechanisms *is used* for performing a first skin-interaction, such as, palpation, occlusion and/or skin-stretching technique which is performed on the skin but the first device… is disposed beneath the skin." (Emphasis added.) The Examiner finds the claim language "confusing" because although these components are beneath the skin, they "are [should] to be used on top of the skin for performing palpation, occlusion, and/or skin-stretching techniques."

Appellants' claims are directed to an apparatus. These apparatus claims should and do recite the various features of an apparatus and the interrelationships between them. Patent law does not require that a claim include language that explains how a user interacts with the claimed features, which is effectively what the Examiner is requiring. Rather, as 35 USC §112 makes clear, such "explanation" is the purpose of the specification, which shall include a written description of how to use the invention in such terms as to enable one skilled in the art to use the invention. As stated in 35 USC §112:

> The specification shall contain a **written description** of the invention, **and of the manner** and process of making and **using it**, in such full, clear, concise, and exact terms **as to enable any person skilled in the art** to which it pertains, or with which it is most nearly connected, **to make and use the same**, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

> The specification shall conclude with **one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention**.
>
> (Emphasis added.)

There is no Section 112, paragraph 2 issues with any of the claims on appeal.

And although the issue was not raised by the Examiner, applicant notes that there are no Section 112, paragraph 1 issues with the case, either.

In particular, appellant's specification is clear about the need/desire for the various mechanisms to be located below the surface of the pseudo skin. And it is also clear that to practice the techniques enabled by the mechanisms, a user interacts (*e.g.*, pushes, stretches, *etc.*) with the pseudo skin:

para. [0040]: "Pseudo skin **220** is a membrane that is used in conjunction with the simulation of skin-interaction techniques, such as palpation, occlusion, and skin stretch techniques…. In some embodiments, pseudo skin **220** is at least somewhat resilient to enable a user to perform skin-interaction techniques."

Para. [0041]: "As depicted in FIG. 3, pseudo skin **220** is accessed for insertion and skin-interaction techniques (*e.g.*, palpation, occlusion, skin stretch, *etc.*) through openings **330** and **332** in housing **216**. Opening **330** defines palpation/occlusion region **331** (*i.e.*, the site at which palpation and occlusion techniques are performed) and opening **332** skin-stretch region **333** (*i.e.*, the site at which the skin-stretch technique is performed) and includes insertion region **334** for the end effector (*e.g.*, needle/catheter module **218**)."

The specification also incorporates by reference related cases that provide further detail about the various skin-interaction mechanisms and their use. All the information that one skilled in the art would need to make and use the invention is provided by the disclosure, consistent with Section 112.

Ground 2. The appellant has argued that gimbal apparatus (25) of Rosenberg is not a device for performing a skin-interaction technique. The Examiner disagrees with appellant's position, noting that the gimbal apparatus "is being used for performing a first skin interaction in the broadest [sense]…." According to the Examiner:

- a first skin interaction can be "any interaction with the skin at this point of the rejection."
- "using the claim language 'for' doing something which is a typical claim language which may not distinguish over the prior art. This is not a positive limitation so the structures only require the ability to so perform which in this case the gimbal apparatus does."

As to the first "bullet" point, the Examiner provides no explanation of how the gimbal apparatus of Rosenberg is being used to perform a skin interaction technique "in the broadest [sense]." It is clear from Rosenberg that gimbal apparatus (25), which does not contact barrier (12), receives the end effector (*i.e.*, laparoscopic tool) and constrains its movements to a specified number of degrees of freedom. There is no interaction between the gimbal apparatus and the pseudo skin at all.

Perhaps the Examiner is suggesting that because the gimbal apparatus receives the laparoscopic tool, wherein the tool is inserted through the barrier (skin), the gimbal apparatus is fairly characterized as performing a skin-interaction technique. The appellant's specification uniformly distinguishes "insertion" of the end effector into a receiver on the one hand, from "skin-interaction" techniques on the other hand. *See,* for example, para. [0041]: "As depicted in FIG. 3, pseudo skin **220** is accessed for insertion **and** skin-interaction techniques (*e.g.*, palpation, occlusion, skin stretch, *etc*.) through openings **330** and **332** in housing **216**." (Emphasis added.)

Patent law is clear that the specification is an appropriate source, if not the primary source, for ascertaining the meaning of claim terms. While terms should be given broadest reasonable interpretation during prosecution, such interpretation is not subject to an Examiner's unfettered discretion. In this context, a "reasonable" interpretation must be consistent with the specification that supports the claims.

MPEP 2111 requires that:

> During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." The Federal Circuit's en banc decision in Phillips v. AWH Corp., 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard:
>
> > The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the

> claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." In re Am. Acad. of Sci. Tech. Ctr., 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." 37 CFR 1.75(d)(1)….
>
> The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. In re Cortright, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999).

In view of appellant's clear statements in the specification as to the intended meaning of the term "skin-interaction technique," any reading of that term that would encompass a receiver of a laparoscopic tool, such as "gimbal apparatus (25)," is an *overly* or *unreasonably* broad reading.

The Examiner's second point (bullet point 2) that "the claim language 'for' doing something … is … typical claim language which [sic] may not distinguish over the prior art" and "is not a positive limitation" is a misleading statement at best and an inaccurate one at worst.

The language from claim 1 in question recites:

> a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion.

The excerpted claim language is certainly a "positive limitation" in the sense that the first device is positively, rather than *inferentially*, recited. It would, however, be correct to characterize the limitation in question as a "functional" limitation. A functional limitation defines something by what it does, rather than by its structure, *etc*.

The Federal Circuit and its predecessor court, the CCPA, have expressively approved of the use of functional limitations in claims.

MPEP 2173.05(g) Functional Limitations:

> A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).
>
> A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step.

To the extent that the Examiner states "the structures [in the claim] only require the ability to perform," the appellant agrees. But appellant *disagrees* with the Examiner's allegation that "the gimbal apparatus does" perform as required by the functional limitation.

A device that would satisfy the excerpted limitation must be: (1) capable of performing a first skin-interaction technique (2) that is used in conjunction with a simulated vascular-access procedure and (3) the first skin-interaction technique must be palpation or occlusion.

It might be convenient for the Examiner to ignore the clause "used in conjunction with a simulated vascular-access procedure," as well as the Markush grouping concerning allowable skin-interaction techniques, but it is incorrect to do so. Each of these clauses represent a portion of applicant's claimed functional definition.

Regarding the first "ignored" clause, as previously discussed, there are different types of "palpation." For example, palpating soft tissue for the presence of a tumor requires a different technique than palpating a vein in conjunction with a vascular-access procedure. A device that is intended to support simulated soft-tissue palpation will not be able to support simulated vein palpation in conjunction with a vascular-access procedure. Indeed, the sensors disclosed by Pugh are not capable of performing palpation as performed in conjunction with vascular-access procedures.

The second "ignored" clause (which limits the skin interaction techniques to "occlusion" or "palpation") would operate, for example, to prevent the first device from including a device that could perform the skin-interaction technique of "skin stretching." That being the case, it is ludicrous to suggest that Rosenberg's gimbal mechanism (25), which does not perform any skin-interaction technique defined by applicant, satisfies the recited limitation.

The Examiner also attempted to rebut other of appellant's arguments, most of which have been discussed already in this *Reply Brief.* For the sake of brevity, such discussions will not be repeated here.

Grounds 3 and 5. The Examiner's rebuttals under "Ground 3" and "Ground 5" are similar to those presented under Ground 2. Appellant's response, which would address the Examiner's confusion regarding "positively-recited" limitations, functional limitations, and the inappropriateness of ignoring words in a claim, has already been presented elsewhere. For brevity, these arguments are not repeated here.

Ground 4. The Examiner issued new grounds of rejection for claim 25, which have been addressed earlier in this *Reply Brief*.

Ground 6. Applicant had demonstrated via appropriate language from Rosenberg that the end effector (*i.e.*, laparoscopic tool) is NOT inserted through the pseudo skin during the performance of a simulated vascular access procedure. In particular, the laparascopic tool is actually inserted before any such simulation actually begins. The Examiner disagrees, but provides no support for her position other than to simply state that "the laparascopic tool has a shaft that is inserted through the pseudo skin during the performance of the simulated vascular-access procedure of Rosenberg." Appellant will not repeat the arguments here; suffice it to say that the disclosure supports appellant's interpretation.

Ground 7. No rebuttals were presented by the Examiner.

Respectfully,

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